

Remarks

Status of Claims

Claims 1, 5-9, 11-16, 18-20, 22, 23 and 28-37 are pending in the application. Claims 13 and 30 have been withdrawn from consideration. Claims 2-4, 10, 17, 21 and 24-27 have been previously canceled. Thus, claims 1, 5-9, 11-12, 14-16, 18-20, 22, 23, 28-29 and 31-37 are presented for examination.

Claims 1, 18 and 22 have been amended to establish terminology that is internally consistent within the claims.

Examiner Interview

As an initial matter, Applicant would like to thank the Examiner for the courtesy of the interview that was extended to Applicant's undersigned representative on February 1, 2011, in which it was agreed that a supplemental Final Office Action would be mailed examining claims 33, 34, and 37. The supplemental Final Office Action was mailed on February 28, 2011 and is being responded to here.¹

Rejection under 35 U.S.C. 103(a)

Claims 1, 5-9, 11-12, 14-16, 18-20, 22-23, 28-29 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk, United States Patent 6,545,097 (Pinchuk), Smith et al., United States Patent 5,639,810 (Smith), and Hamilton et al., United States Patent, 6,896,842 (Hamilton). Applicant respectfully traverses this rejection.

For a proper obviousness rejection under 35 U.S.C. 103, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. “ ‘[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’ ” *KSR International*

¹ It was further confirmed in a telephone call to the Examiner on April 13, 2011 that the prior Final Office Action dated December 13, 2010 was voided by the supplemental Final Office Action of February 28, 2011, and that the time period for a response is the time period stated in the supplemental Final Office Action.

Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn*, 441 F.3d 977, 988, (Fed. Cir. 2006). It should be noted that the prior art reference (or references when combined) must teach or suggest all the claimed features. “When determining whether a claim is obvious, an examiner must make ‘a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.’ ... Thus, ‘obviousness requires a suggestion of all limitations in a claim.’ ...” *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, January 14, 2008 (emphasis in original) (citations omitted). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

Independent claim 1, the only independent claim presently pending, is directed to an implantable or insertable medical device comprising (a) a therapeutic agent and (b) *a polymeric carrier region that comprises said therapeutic agent and which releases said therapeutic agent upon administration to a patient*, said polymeric carrier region comprising *a silicone block copolymer* comprising a plurality of siloxane units and a plurality of non-siloxane units, said block copolymer *comprising (i) a block of said siloxane units* selected from a polydimethylsiloxane block, a polydiethylsiloxane block, a polymethylethylsiloxane block and a polymethylphenylsiloxane block *and (ii) a block of elevated T_g non-siloxane units*, wherein the polymeric carrier region is in the form of a coating layer that covers all or a part of said medical device.

According to the Office Action, Pinchuk teaches, *inter alia*, a composition for delivering therapeutic agents such as paclitaxel, which comprises a block copolymer made up of an elastomeric block and a thermoplastic block, and is used to coat at least a portion of an intravascular or intervascular medical device such as stent.

The Office Action notes that Pinchuk does not teach wherein the elastomeric block comprises polydimethylsiloxane, but urges (a) that Smith teaches thermoplastic block copolymers having methylstyrene end blocks and polydimethylsiloxane (elastomeric) intermediate blocks and (b) that Smith teaches that the elastomeric materials are useful for medical and therapeutic device applications.

More specifically, Smith describes internally lubricated elastomers useful in therapeutic or medical device applications as penetrable septa, membranes or like barrier or sealing materials (see Title, Abstract and col. 8, lines 16-18). The block copolymer specifically taught

by Smith for use in such applications is a styrene-ethylene/butylene-styrene block copolymer (see, e.g., claims 21, 47, 55 and 62, col. 2, lines 45-49, col. 8, lines 5-7 and 49-51, etc.).

Smith at col. 4 lines 48 *et seq.* describes several prior art references which “may also be considered relevant to the present invention” including U.S. Pat. No. 4,123,409 to Kaelble. As an initial matter, it is noted that this portion of Smith pertains to background prior art references.

Smith notes that Kaelble describes a thermoplastic elastomer sealing material for contact with animal tissue, which is made by mixing a high molecular weight non-volatile oil in at least a ratio of 1 to 1 with a block copolymer. Articles made with these materials are said to combine conformability and flexibility with adherence strength and resistance to tearing. In one embodiment (referred to in the Office Action), thermoplastic block copolymers having polyalphamethylstyrene end blocks and polydimethylsiloxane intermediate blocks are combined with silicone oil. The specific silicone oil used in Kaelble is DC200 (Dow Corning 200) silicone oil, otherwise known as polydimethylsiloxane (see Kaelble at col. 5, lines 58-68 and the data sheet on DC200, of record, attached to Applicant’s previous response dated October 19, 2010).

Thus, the materials in Smith are barrier or sealing materials. Barrier and sealing materials, while useful for many medical applications, are clearly inappropriate for forming polymeric carrier regions like those claimed which comprise a therapeutic agent and which release the therapeutic agent upon administration to a patient. In fact, by their very nature, a barrier or sealing material is the very antithesis of a therapeutic-agent-releasing polymeric carrier. In this way, Smith teaches away from the present invention.

The concept of using a silicone block copolymer comprising a plurality of siloxane units and a plurality of elevated T_g non-siloxane units copolymers in polymeric carrier regions which comprise a therapeutic agent and which release the therapeutic agent upon administration to a patient is Applicant’s concept and is unobvious in view of the prior art.

As stated in MPEP 2142: “The tendency to resort to “hindsight” based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” Here, the prior art does not support a conclusion of obviousness absent the hindsight gained from Applicant’s disclosure.

Hamilton, which is cited for its teaching that thermoplastic elastomers for medical devices are resistant to radiation and can thus be sterilized by radiation, does not make up for the above-noted deficiencies in Pinchuk and Smith.

It is further noted that Hamilton states the following at col. 3, lines 54-62 (cited in the Office Action):

The preferred TPEs for the balloon described herein are engineering thermoplastic elastomers (ETEs), which are randomized block copolymers having polyester crystalline hard segments and amorphous glycol soft segments. ETEs possess flexibility over a useful range of strain, and are quite extensible when operating within their elastic limit. Another advantage of ETEs for medical devices is their resistance to most radiation, permitting sterilization by such means, although they must be protected from UV radiation.

Thus the engineering thermoplastic elastomers (ETEs) referred to by Hamilton as being resistant to most radiation are randomized block copolymers having polyester crystalline hard segments and amorphous glycol soft segments. Such copolymers are, however, irrelevant to those of Pinchuk and Smith (and to those claimed).

For at least the preceding reasons, claim 1, as well as claims 5-9, 11-12, 14-16, 18-20, 22, 23, 28-29 and 31-37 depending therefrom, are unobvious over Pinchuk, Smith and Hamilton.

It is further seen from the above discussion that Smith (via a description of Klaeble as prior art) teaches combining thermoplastic block copolymers having polyaliphathylstyrene end blocks and polydimethylsiloxane intermediate blocks with silicone oil (i.e., polydimethylsiloxane) in order to produce an article that combines “conformability and flexibility with adherence strength and resistance to tearing” (Smith, col. 4, line 67 to col. 5, line 5). Thus, a *combination* of the thermoplastic block copolymer with a supplemental silicone polymer is required to provide an article with good strength and resistance to tearing—the very properties that the Office Action alleges would have provided motivation to modify Pinchuk with the teachings of Smith (Office Action, page 5).

In dependent claim 33, on the other hand, the polymeric carrier region does *not* comprise a supplemental polymer. In dependent claims 34 and 37, the polymeric carrier region does *not* comprise a supplemental silicone polymer. Thus, claims 33, 34 and 37 are unobvious over Pinchuk, Smith and Hamilton for at least this additional reason.

For at least the above reasons, claims 1, 5-9, 11-12, 14-16, 18-20, 22, 23, 28-29 and 31-37 are patentable over Pinchuk, Smith and Hamilton.

Conclusion

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at (703) 433-0510 in order that any outstanding issues be resolved.

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Respectfully submitted,

Attorney for Applicants
Mayer & Williams PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
703-433-0510 Tel.
908-518-7795 Fax

By /David B. Bonham/
David B. Bonham
Registration No.: 34,297